K031581

GREEN PROSPECT SDN. BHD. (567515-D)

JUL 2 4 2003

APPENDIX-K

1.0 SMDA 510 (K) SUMMARY

2.0 Submitter

Green Prospect Sdn Bhd
Lot 14803, Kawasan Perindustrian
Kg. Acheh, Sitiawan, Lumut
Perak Darul Ridzuan
MALAYSIA

Tel 605-6911288

Fax 605-6922388

Name of Contact Person 1. MS. WONG YOKE CHENG

Date of Summary Prepared March 20, 2003

3.0 Name of Device

Trade Name : Non-Sterile Powder Free, Latex Examination Gloves, Polymer Coated White Color, with Protein Labeling, Contains 50 Micrograms or Less of Total Water Extractable Protein Per Gram
(Multiple Private Labels)

Common Name Exam Glove

Classification Name Patient Examination Glove

4.0 Identification of The Legally Marketed Devices

Class 1 Latex Patient Examination Glove 80 LYY, powder free that meets all the requirements of ASTM Standard D3578-01 and FDA requirements.

5.0 Description of The Device

Class 1 Latex Patient Examination Glove 80 LYY, powder free that meets all the requirements of ASTM Standard D3578-01 and FDA Water leak test.

6.0 The Intended Use of Glove

A medical glove is worn on the hand of healthcare and similar personnel to prevent contamination between healthcare personnel and the patient's body, fluids, waste or environment.

Lot 14803, Kawasan Perindustrian, Kampung Acheh, 32000 Sitiawan, Perak Darul Ridzuan, Malaysia.
Tel: 05-6911288 (Hunting Line) Fax: 05-6922388

K031581

7.0 Summary of Performance Data:

Performance data of gloves based on ASTM D3578-01 and FDA 1000ML watertight test.

TEST	ASTM D3578-01	POWDER FREE LATEX EXAM. GLOVES
1. Watertight (1000ml)	Multiple Normal GI AQL = 2.5	Pass GI AQL = 2.5
2. Length (mm) Size XS S M L XL	 Min 220 Min 220 Min 230 Min 230 -	 240 mm minimum for all sizes
3. Palm width (mm) Size XS S M L XL	 70 ± 10 80 ± 10 95 ± 10 111 ± 10 -	 73 – 78 83 – 88 93 – 98 103 – 107
4. Thickness (mm) (Single Layer) Finger Palm	 Min 0.08 Min 0.08	 Min 0.10 Min 0.10
5. Physical Properties Before Aging Tensile Strength (MPa) Ultimate Elongation (%) Stress at 500% Elongation After Aging Tensile Strength (MPa) Ultimate Elongation (%)	 Min 18 Min 650 Max 5.5 Min 14 Min 500	 22 – 24 820 – 900 2.2-2.9 22 – 24 800 – 860
6. Powder Content	Max 2.0mg/glove	Below 2 mg/glove
7. Protein Content	Max 50 microgram/gram	Below 50 microgram/gram

8.0 The performance data of the glove as shown above meet the ASTM D3578-01 Standard and FDA's requirement.
Powder content is below 2 mg per glove which meet the FDA Requirements.
The protein content tested on accelerated aging gloves is ≤ 50 mg/gram.

9.0 The Bio-compatibility Test consists of Primary Dermal Irritation Test and Guinea Pig Sensitization (Buehler) test.
The gloves pass the Bio-compatibility Test.

10.0 Conclusion

We concluded that the Multiple Private Labeled Non-Sterile Powder Free, Latex Examination Gloves, Polymer Coated Natural and/or Colored with Protein Labeling, Contains 50 Micrograms or Less of Total Water Extractable Protein Per Gram meets:

- ASTM D3578-01 Standard
- FDA pinhole requirements
- FDA minimum Powder Residual Content.
- Label Claim of maximum 50 micrograms per gram of glove or less for water Extractable Protein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 2003

Green Prospect Sdn Bhd
C/O Ms. Janna P. Tucker
Tucker & Associates
198 Avenue De La D'emerald
Sparks, Nevada 89434-9550

Re: K031581
Trade/Device Name: Non-Sterile Powder Free, Latex Examination Gloves, Polymer Coated White Color with Protein Labeling, Contains 50 Micrograms or Less of Total Water Extractable Protein Per Gram
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: July 3, 2003
Received: July 7, 2003

Dear Ms. Tucker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

Applicant: Green Prospect Sdn Bhd

510K Number: K031581

Device Name: Non-Sterile Powder Free , Latex Examination Gloves, Polymer Coated White Color, with Protein Labeling, Contains 50 Micrograms or Less of Total Water Extractable Protein Per Gram

Indications for Use:

This is a medical glove to be worn on the hand of health care and similar personnel to prevent contamination between health care personnel and the patient.

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031581

Prescription Use ..... OR Over-The-Counter .....
Per 21 CFR 801.109